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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,243	11/18/2003	Marc D. Better	11022US16	8820

7590 07/05/2005

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,243	BETTER ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13 are pending and are being acted upon in this Office Action.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "he3" in claims 3-9 is indefinite because "he3" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation s to define completely distinct antibody.

The "SEQ ID NO: 2 *and* 101 and an antibody" in claim 1 is ambiguous and indefinite because the specification discloses a fusion protein comprising gelonine as set forth in SEQ ID NO: 2 *or* 101 and an antibody or an antigen binding fragment of an antibody (page 69). It is suggested that claim 1 be amended to recite "A fusion protein comprising gelonin as set forth in SEQ ID NO: 2 or 101 and an antibody or an antigen binding fragment thereof. Since "region of an antibody comprising an antigen binding portion" in claim 1 will be replace with "antigen binding fragment", the "said region" in claims 4-13 should also be replace with "said antigen binding fragment".

"said antibody *of* said region" in claim 11 should have been "said antibody *or* said region".

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,649,742 B1 (Nov 18, 2003; PTO 892). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 1 of instant application recites a fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion (genus). The said antibody or said region in the fusion protein can be fused to either the amino terminus or the carboxyl terminus of gelonin. Claim 1 of the '742 patent recites a fusion protein comprising gelonin as in SEQ ID NO: 2 or 101 and an antibody or region of an antibody comprising an antigen-binding protein, wherein said antibody or said region is fused to the amino terminus or the carboxyl terminus of gelonin (species). Claim 11 of the '742 patent recites a fusion protein comprising gelonin as in SEQ ID NO: 2 or 101 and an antibody or region of an antibody comprising an antigen-binding protein, wherein said antibody or said region is fused to the carboxyl terminus or the carboxyl terminus of gelonin (species). The issuance of a patent to instant application (genus) would include the species of the issued patent. The species (issued) patent anticipates the genus (instant application).

Claim 2 of instant application recites the fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion wherein said antibody or said region is fused to the carboxyl terminus of said gelonin, which is identical to claim 11 of the '742 patent.

Claim 12 of instant application recites the fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion wherein said antibody or said region is fused to the amino terminus of said gelonin, which is identical to claim 1 of the '742 patent.

Claims 3-9 of instant application recites the fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion wherein said antibody is an he3 antibody (species), he-3 Fab fragment, he3 Fd fragment, he3 F(ab')2 fragment, he3 kappa fragment, and he3 single-chain antibody, respectively (species). Claims 3-8 of '742 patent recites the fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion wherein said antibody or said region is fused to the amino terminus of gelonin and said antibody is an antibody (genus), an Fab fragment, an Fd fragment, an F(ab')2 fragment, an kappa fragment, and an single-chain antibody, respectively (genus). Claims 13-18 of the '742 patent recites the fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion wherein said antibody or said region is fused to the carboxyl terminus of gelonin and said antibody is an antibody (genus), an Fab fragment, an Fd fragment, an F(ab')2 fragment, an kappa fragment, and an single-chain antibody, respectively (genus). The species anticipates the genus.

6. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,621,083 (April 15, 1997; PTO 892). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 1 of instant application recites a fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion (genus). The said antibody or said region in the fusion protein can be fused to either the amino terminus or the carboxyl terminus of gelonin. Claim 1 of '083 patent recites a fusion protein comprising a toxin sequence that is gelonin SEQ ID NO: 2 or 101 and a targeting sequence comprising an antibody variable domain specifically reactive with a human CD5 antigen recognized by an antibody having a heavy chain variable region sequence that is SEQ IDNO: 126 and light chain variable region that is SEQ ID NO: 125 (species). Claim 2 of the '083 patent recites the fusion protein comprising a toxin sequence that is gelonin SEQ ID NO: 2 or 101 and a targeting sequence comprising an antibody variable domain specifically reactive with a human CD5 antigen recognized by an antibody having a heavy chain variable region sequence that is SEQ IDNO: 126 and light chain variable region that is SEQ ID NO: 125 wherein the toxin sequence is SEQ ID NO: 2 (species). Claim 3 of the '083 patent recites the fusion protein

comprising a toxin sequence that is gelonin SEQ ID NO: 2 or 101 and a targeting sequence comprising an antibody variable domain specifically reactive with a human CD5 antigen recognized by an antibody having a heavy chain variable region sequence that is SEQ IDNO: 126 and light chain variable region that is SEQ ID NO: 125 wherein said toxin sequence is SEQ ID NO: 101 (species). The issuance of a patent to instant application (genus) would include the species of the issued patent. The species (issued) patent anticipates the genus (instant application).

Claims 3-9 of instant application recites the fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion wherein said antibody is an he3 antibody (species), he-3 Fab fragment, he3 Fd fragment, he3 F(ab')2 fragment, he3 kappa fragment, and he3 single-chain antibody, respectively (species). The gelonin toxins of SEQ ID NO: 2 or 101 in the fusion protein of instant application are the same as toxin gelonin of SEQ ID NO: 2 or 101 in the fusion protein in claim 1 of the issued patent. The he3 antibody of instant application appears to be same "he3 antibody" in the fusion protein as that of claim1, 7-10 of the '083 patent since instant application is a continuation of the issued patent.

Claim 10 of instant application recites the fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion wherein antibody or said region is fused to the carboxyl terminus of said gelonin further comprising a peptide segment of a rabbit muscle aldolase as in SEQ ID NO: 56 between said gelonin and said antibody or said region.

Claim 11 of instant application recites the fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion wherein antibody or said region is fused to the carboxyl terminus of said gelonin further comprising a peptide segment of a rabbit muscle aldolase as in SEQ ID NO: 57 between said gelonin and said antibody or said region (genus). However, Claim 4 of the '083 patent recites the fusion protein comprising a toxin sequence that is gelonin SEQ ID NO: 2 or 101 and a targeting sequence comprising an antibody variable domain specifically reactive with a human CD5 antigen recognized by an antibody having a heavy chain variable region sequence that is SEQ IDNO: 126 and light chain variable region that is SEQ ID NO: 125 further comprising a linker sequence between said toxin sequence and said targeting sequence that is linker SEQ ID NO: 56 or SEQ ID NO: 57 (species). The same reasons apply to claims 5-6 of the '083 patent.

The issuance of a patent to instant application would include the fusion protein (species) of the '083 patent.

7. Claims 1-2 and 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,744,580 (April 28, 1998; PTO 892). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 1 of instant application recites a fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion (genus). The said antibody or said region in the fusion protein can be fused to either the amino terminus or the carboxyl terminus of gelonin. Claim 1 of '580 patent recites a fusion protein comprising (a) a gelonin sequence that is SEQ ID NO: 2 or SEQ ID NO: 101 and a targeting sequence that allows the internalization of said fusion protein, wherein said targeting sequence is an antibody, an antigen-binding portion of an antibody, a hormone, a lymphokine or a growth factor (subgenus). The issuance of a patent to instant application would include the subgenus of fusion protein comprising the gelonin sequence that is SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or antigen binding portion of an antibody of claim 1 of '580 patent. The antibody in the fusion protein of the '580 patent could be fused to either the N terminus or the C terminus of gelonine, which obviously would include claim 2 of instant application, which recites the fusion protein wherein said antibody or said region is fused to the carboxyl terminus of said gelonin, or claim 12 of instant application which recites the fusion protein wherein said antibody or said region is fused to the amino terminus of said gelonin. The fusion protein of instant application further comprises a linker of SEQ ID NO: 57 (claim 11) which anticipates the fusion protein further comprises linker sequence of SEQ ID NO: 56 of the '580 patent (claim 5). Claims 8-10 of the '580 patent are included in this rejection because Fab, Fab', F(ab')sub2 are all antigen binding portion of an antibody in the fusion protein.

8. Claims 1-2, and 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 14 of U.S. Patent No. 6,376,217 B1 (April 23, 2002; PTO 892). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 1 of instant application recites a fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion (species). The said antibody or said region in the fusion protein can be fused to either the amino terminus or the carboxyl terminus of gelonin. Claim 1 of '217 patent recites a fusion protein comprising (a) a gelonin amino acid sequence that has enzymatic activity and (g) a targeting sequence that allows the internalization of said fusion protein, wherein said targeting sequence is an antibody, an antigen-binding portion of an antibody, a hormone, a lymphokine or a growth factor (genus). An issuance of a patent to instant application (species) would anticipate the genus fusion protein of the '217 patent. The antibody in the fusion protein of the '217 patent could be fused to either the N terminus or the C terminus of gelonine, which obviously would include claim 2 of instant application, which recites the fusion protein wherein said antibody or said region is fused to the carboxyl terminus of said gelonin, or claim 12 of instant application which recites the fusion protein wherein said antibody or said region is fused to the amino terminus of said gelonin. The fusion protein of instant application further comprises a linker of SEQ ID NO: 57 (claim 11) which anticipates the fusion protein further comprises linker sequence of SEQ ID NO: 56 of the '217 patent (claim 3). Claims 5-8 of the '217 patent are included in this rejection because Fab, Fab', F(ab')sub2 are all antigen binding portion of an antibody in the fusion protein.

9. Claims 1-2, and 10-11 are directed to an invention not patentably distinct from claims 1-8 and 14 of commonly assigned of U.S. Patent No. 6,376,217 B1 (April 23, 2002; PTO 892). Specifically, Claim 1 of instant application recites a fusion protein comprising gelonin as in SEQ ID NO: 2 or SEQ ID NO: 101 and an antibody or region of an antibody comprising an antigen binding portion (species). The said antibody or said region in the fusion protein can be fused to either the amino terminus or the carboxyl terminus of gelonin. Claim 1 of commonly assigned '217 patent recites a fusion protein comprising (a) a gelonin amino acid sequence that has enzymatic activity and (g) a targeting sequence that allows the internalization of said fusion protein, wherein said targeting sequence is an antibody, an antigen-binding portion of an antibody, a hormone, a lymphokine or a growth factor (genus). An issuance of a patent to instant application (species) would anticipate the genus fusion protein of the '217 patent. The antibody in the fusion protein of the '217 patent could be fused to either the N terminus or the C terminus of gelonine, which obviously would include claim 2 of instant application, which recites the fusion protein wherein said antibody or

said region is fused to the carboxyl terminus of said gelonin, or claim 12 of instant application which recites the fusion protein wherein said antibody or said region is fused to the amino terminus of said gelonin. The fusion protein of instant application further comprises a linker of SEQ ID NO: 57 (claim 11) which anticipates the fusion protein further comprises linker sequence of SEQ ID NO: 56 of the '217 patent (claim 3). Claims 5-8 of the '217 patent are included in this rejection because Fab, Fab', F(ab')sub2 are all antigen binding portion of an antibody in the fusion protein.

10. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,376,217 B1 (April 23, 2002; PTO 892), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

13. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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